

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Phillips et al.

Serial No.: 09/857,332

Filing Date: June 4, 2001

For: **Chemotherapeutic Composition and Method**



Examiner: J. Eric Angell

Art Unit: 1635

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

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Sir:

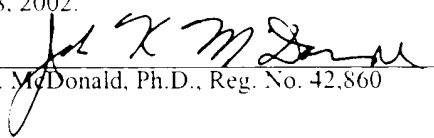
In response to the Restriction Requirement mailed February 6, 2002, in the above-identified patent application, Applicants provisionally elect to prosecute the invention of Group V, Claims 25, 28, and 31, drawn to a method of treating cancer comprising administration of a composition comprising a *mycobacterium* cell wall (MCC). This election is made with traverse.

The Restriction Requirement is respectfully traversed. The Examiner states:

"The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The groups are related because each group encompasses fractionated *mycobacterium* (i.e. DNA or cell wall fractions) in a composition for chemotherapeutic use. However, it was known in the art at the time of filing that

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, DC 20231, on April 8, 2002.


John K. McDonald, Ph.D., Reg. No. 42,860

fractions of *mycobacterium* could be useful in treating tumors (see Shimada et al., The Journal of The National Cancer Institute, March 1985, 74(3)681-8, cited as an "X" reference in the published International Search Report). Therefore, no special technical feature links the Inventions and restriction is proper."

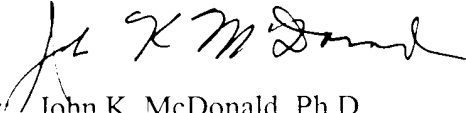
Applicants respectfully submit that the inventions encompassing a composition comprising a *mycobacterium* DNA (M-DNA), and encompassing a composition comprising a *mycobacterium* cell wall (MCC) relate to a single general inventive concept under PCT rules 13.1 and 13.2. As used in the present invention, *mycobacterium* cell wall (MCC) is defined on page 5, lines 35-36 of the specification as "M-DNA preserved and **complexed** on deproteinized and delipidated *M. Phlei* cell wall" (emphasis added). Therefore, as defined in the present application, M-DNA is an inherent component of MCC. Thus, M-DNA and MCC are united by a common special technical feature, and are not merely two separate fractions of *mycobacterium*. In contrast, Shimada *et al.* teaches a fraction "extracted from BCG and composed of 70.0% DNA and 28.0% RNA" (see Abstract). Based on the above remarks, Applicants respectfully submit that the search and examination of a method comprising administration of a composition comprising a *mycobacterium* cell wall and a method comprising administration of a composition comprising a *mycobacterium* DNA can be made without serious burden. MPEP §803 states that "if the search and examination of the entire application can be made without serious burden, the Examiner must examine it on the merits". Accordingly, Applicants request the withdrawal of the Restriction Requirement and examination of the application on the merits.

This Response to the Restriction Requirement is fully responsive and timely filed in view of the concurrently filed petition for a one-month extension of time and the required fee. Applicants respectfully request reconsideration of the present application in view of the foregoing remarks. Such action is courteously solicited. Applicants further request that the Examiner contact the undersigned attorney if any questions arise concerning this Response to the

Restriction Requirement. The direct telephone number for the undersigned attorney is 404-745-2470.

No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

Respectfully submitted,


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